

Amended Claims 1-33 Submitted to IPEA on Nov 20, 2000
Under Article 34

- 5 1. A soft capsule comprising fill material filling a shell,
wherein the fill material is in a solid or semi-solid form
at room temperature.
- 10 2. A soft capsule according to claim 1, wherein the soft
capsule is a chewable capsule.
3. A soft capsule according to claim 1, wherein the fill
material comprises a low melting point additive.
- 15 4. A soft capsule according to claim 3, wherein the content
of the low melting point additive is 10% or more with respect
to the total weight of the fill material.
- 20 5. A soft capsule according to claim 4, wherein the content
of the low melting point additive is 30% or more with respect
to the total weight of the fill material.
- 25 6. A soft capsule according to claim 5, wherein the content
of the low melting point additive is 50% or more with respect
to the total weight of the fill material.
7. A soft capsule according to any of claims 3 to 6, wherein
the melting point of the low melting point additive is about
20 to 50°C.
- 30 8. A soft capsule according to any of claims 3 to 6, wherein
the low melting point additive is selected from the group
consisting of chocolate base, lard, coconut oil and macrogol
as well as a combination thereof.

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9. A soft capsule according to claim 8, wherein the low melting point additive is a chocolate base.
10. A soft capsule according to claim 9, wherein the chocolate base is selected from the group consisting of cacao powder, bitter chocolate and cacao butter as well as a combination thereof.
11. A soft capsule according to claim 10, wherein the cacao butter includes a major amount of V-type crystal and a minor amount of VI-type crystal. ??
12. A soft capsule according to claim 1 or 3, wherein the fill material further comprises a sweetening agent.
13. A soft capsule according to claim 12, wherein the sweetening agent is selected from the group consisting of aspartame, disodium glycyrrhizinate, saccharin sodium, stevia and thaumatin as well as a combination thereof.
14. A soft capsule according to claim 13, wherein the fill material comprises cacao butter as chocolate base, which is a low melting point additive, and aspartame as a sweetening agent.
15. A soft capsule according to claim 12, wherein the fill material further comprises a saccharide.
16. A soft capsule according to claim 15, wherein the saccharide is selected from the group consisting of sucrose, D-mannitol, xylitol, erythritol, D-sorbitol, maltose, reduced maltose syrup and maltitol as well as a combination

thereof.

17 A soft capsule according to claim 12, wherein the fill material further comprises an aromatic.

18 A soft capsule according to claim 17, wherein the aromatic is chocolate flavor.

19 A soft capsule according to any of claims 1 to 18, wherein

the shell comprises the following components (A) and (B):

(A) gelatin; and

(B) one or more plasticizers selected from (b1) to (b3), wherein a total of 100 to 600 weight parts of the plasticizers is present in the shell with respect to 100 weight parts of gelatin:

(b1) glycerin,

(b2) saccharide plasticizer selected from the group consisting of sucrose, fructose, D-mannitol, xylitol, erythritol, D-sorbitol, maltose, reduced maltose syrup, maltitol, sucrose alcohol and isomerized sugar as well as a combination thereof, and

(b3) glycol selected from the group consisting of propylene glycol and polyethylene glycol as well as a combination thereof.

20 A soft capsule according to claim 19, wherein the plasticizers (B) include the glycerin (b1).

21 A soft capsule according to claim 19, wherein the shell further comprises (C) water-insoluble cellulose, wherein 5 to 100 weight parts of water-insoluble cellulose is present

shell
gelatin
+
plasticizer.

in the shell with respect to 100 weight parts of the gelatin.

~~22.~~ A soft capsule according to claim 19, wherein the shell further comprises (D) a sweetener.

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23. A soft capsule according to claim 22, wherein the sweetener (D) is selected from the group consisting of saccharin sodium, stevia and thaumatin as well as a combination thereof.

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~~24.~~ A soft capsule according to any of claims 1 to 23, wherein the fill material comprises a drug. improper

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~~25.~~ A soft capsule according to claim 24, wherein the content of the drug is 60% or less with respect to the total weight of the fill material. 103 - %

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~~26.~~ A soft capsule according to claim 25, wherein the drug is selected from the group consisting of an antipyretic analgesic drug component, a rhinitis drug component, an antitussive expectorant drug component and a vitamin component as well as a combination thereof. drugs

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~~27.~~ A soft capsule according to any of claims 1 to 23, wherein the fill material comprises a food.

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~~28.~~ A method for producing a soft capsule according to any of claims 1 to 27, comprising the step of:
filling the shell with the fill material. improper multiple

29. A method according to claim 28, wherein the fill material comprises cacao butter as chocolate base, which is a low melting point additive, and the method further dependent.
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subjecting the fill material filling in the shell to aging at a temperature of 30 to 40°C.

- 5 30. A method according to claim 29, wherein the aging is
conducted for 10 hours or more.
- 31. (Added) A soft capsule according to claim 8, wherein
the low melting point additive is lard.
- 10 32. (Added) A soft capsule according to claim 8, wherein
the low melting point additive is coconut oil.
- 33. (Added) A soft capsule according to claim 8, wherein
15 the low melting point additive is macrogol.

(B) one or more plasticizers selected from (b1) to (b3), wherein a total of 100 to 600 weight parts of the plasticizers is present in the shell with respect to 100 weight parts of gelatin:

(b1) glycerin,

(b2) saccharide plasticizer selected from the group consisting of sucrose, fructose, D-mannitol, xylitol, erythritol, D-sorbitol, maltose, reduced maltose syrup, maltitol, sucrose alcohol and isomerized sugar as well as a combination thereof, and

(b3) glycol selected from the group consisting of propylene glycol and polyethylene glycol as well as a combination thereof.

24. A soft capsule according to claim 1, wherein the fill material comprises a drug.

27. A soft capsule according to claim 1, wherein the fill material comprises a food.

28. A method for producing a soft capsule according to claim 1, comprising the step of:

filling the shell with the fill material.